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Development of an *in vitro* testing battery to assess biocompatibility of medical devices

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In order to guarantee safety for the end-users of medical devices, they have to be tested for adverse reactions on the skin before market authorization. Animal testing is still state of the art, but ethically questionable and expensive. During the last years, socio-political pressure has led to the development of alternatives. One of the key aspects of our recent research is to establish an *in vitro* testing battery to examine the biocompatibility of medical devices in contact with the skin or mucosa. The first task was the development of an appropriate extraction method in order to cover a wide range of substances migrating from the device. As skin models and various assays have already been developed for testing pure chemicals, the focus was on the establishment of such methods to assess extracts for cytotoxicity, irritation and sensitization. To identify a possible sensitization potential, a screening method to cover different steps of the skin sensitization process was developed. The molecular initiation event, the binding of haptens to peptides can be assessed by chromatographic methods. The molecular and cellular responses include the activation of an antioxidant pathway in keratinocytes and hence, activating the phenotypical deformation of dendritic cells. So far, various samples have been examined in the different assays. Spiking of sample extracts was used to prevent false negative results. Additionally, samples were examined with animal testing in order to compare the results which showed more sensitive responses in the *in vitro* assays. Further, it could be shown that not only materials themselves but also the manufacturing process plays an important role for biocompatibility. In this context, production processes of medical devices were improved. Summarizing, these assays are developed not only with a sufficient sensitivity, but also to be robust, simple to use, ethically responsible and inexpensive in comparison to current animal testing.

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